

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

FOREST SPEAKS,)	
)	
Plaintiff,)	
)	
v.)	
)	CASE NO.: 2:05 cv 873-B
ELI LILLY AND COMPANY,)	
)	Jury Trial Demanded
Defendant.)	
)	
)	

ANSWER OF DEFENDANT ELI LILLY AND COMPANY

Defendant Eli Lilly and Company ("Lilly"), by its counsel, hereby responds to plaintiff's Complaint as follows:

STATEMENT OF PARTIES

1. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 1 of the Complaint.

2. Lilly denies the allegations contained in Paragraph 2 of the Complaint, except admits that (1) Lilly is a corporation organized and existing under the laws of the State of Indiana, with its principal place of business in Indianapolis, Indiana, and that at certain times it has been authorized to do business in the State of Alabama, and within this judicial district and (2) Lilly researched, tested, developed, manufactured, marketed and sold Zyprexa® to independent pharmaceutical wholesalers.

JURISDICTION AND VENUE

3. The allegations contained in Paragraph 3 of the Complaint state conclusions of law to which no responsive pleading is required, except that Lilly admits that at

certain times it has been authorized to do business within this judicial district, and Lilly admits that Forest Speaks is a resident of the State of Alabama.

4. The allegations contained in Paragraph 4 of the Complaint state conclusions of law to which no responsive pleading is required, except Lilly is without knowledge or information sufficient to form a belief about the locations of events giving rise to these claims.

FACTUAL ALLEGATIONS

5. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 5 of the Complaint.

6. Lilly denies the allegations contained in Paragraph 6 of the Complaint.

7. Lilly denies the allegations contained in Paragraph 7 of the Complaint.

8. Lilly denies the allegations contained in Paragraph 8 of the Complaint.

9. Lilly denies the allegations contained in Paragraph 9 of the Complaint, except admits that except admits that (1) Zyprexa® is an atypical antipsychotic and (2) Zyprexa® is approved by the FDA for the treatment of schizophrenia, the treatment of acute mixed or manic episodes associated with Bipolar I disorder and maintenance monotherapy for bipolar disorder. By way of further response, it is admitted that Zyprexa® with Lithium or Valproate is indicated, in combination, for the short term treatment of acute manic episodes associated with Bipolar I disorder.

10. Lilly denies the allegations contained in Paragraph 10 of the Complaint, except admits that Lilly researched, tested, developed, manufactured, labeled, marketed and sold Zyprexa® to independent pharmaceutical wholesalers.

11. Lilly denies the allegations contained in Paragraph 11 of the Complaint, except admits that, after receiving FDA approval to market Zyprexa® for the treatment of schizophrenia, the treatment of acute mixed or manic episodes associated with Bipolar I Disorder, and maintenance monotherapy for bipolar disorder, it marketed Zyprexa® for use only on prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings regarding the risks and benefits of the medication.

12. Lilly denies the allegations contained in Paragraph 12 of the Complaint.

13. Lilly denies the allegations contained in Paragraph 13 of the Complaint, except admits that Lilly has marketed Zyprexa® to physicians in the United States in accordance with applicable laws and regulations, with adequate communication of known risks, and with adequate warnings commensurate with the risk and gravity of the possible side effects from its use.

14. Lilly denies the allegations contained in Paragraph 14 of the Complaint, except admits that Lilly has marketed Zyprexa® to physicians in the United States in accordance with applicable laws and regulations, with adequate communication of known risks, and with adequate warnings commensurate with the risk and gravity of the possible side effects from its use.

15. Lilly denies the allegations contained in Paragraph 15 of the Complaint, except admits that information regarding the safety profile of Zyprexa® was contained in FDA-approved labeling for Zyprexa®. Any characterization of the Zyprexa® product labeling that is inconsistent with the FDA-approved labeling for Zyprexa® when the labeling is read in its entirety is denied.

16. Lilly denies the allegations contained in Paragraph 16 of the Complaint.

17. Lilly is without knowledge as to the plaintiff's meaning of the term "total profits," and therefore denies the allegations contained in Paragraph 17 of the Complaint.

18. Lilly denies the allegations contained in Paragraph 18 of the Complaint.

19. Lilly denies the allegations contained in Paragraph 19 of the Complaint, except is without knowledge or information sufficient to form a belief about the plaintiff's knowledge of the safety profile of Zyprexa®.

20. Lilly denies the allegations contained in Paragraph 20 of the Complaint.

21. Lilly denies the allegations contained in Paragraph 21 of the Complaint.

22. Lilly denies the allegations contained in Paragraph 22 of the Complaint.

ANSWERING THE FIRST CAUSE OF ACTION
[ALABAMA EXTENDED MANUFACTURER'S LIABILITY DOCTRINE]

23. Lilly repeats and realleges with the same force and effect as if fully set forth herein its answer to each and every allegation contained in each paragraph incorporated by reference in Paragraph 23 of the Complaint.

24. Lilly denies the allegations contained in Paragraph 24 of the Complaint, except admits that Lilly researched, tested, developed, manufactured, marketed and sold Zyprexa® to independent pharmaceutical wholesalers.

25. Lilly denies the allegations contained in Paragraph 25 of the Complaint, except admits that Lilly researched, tested, developed, manufactured, labeled, marketed and sold Zyprexa® to independent pharmaceutical wholesalers. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 25 of the Complaint relating to the condition in which Zyprexa® reached consumers.

26. Lilly denies the allegations contained in Paragraph 26 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations relating to the plaintiff.

27. Lilly denies the allegations contained in Paragraph 27 of the Complaint, except admits that information regarding the safety profile of Zyprexa® was contained in the FDA-approved labeling for Zyprexa®. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 27 of the Complaint relating to the plaintiff.

28. Lilly denies the allegations contained in Paragraph 28 of the complaint.

WHEREFORE, defendant Eli Lilly and Company requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that Lilly be awarded the costs, disbursements, and attorney's fees incurred in the defense of this action, and that Lilly be granted any other relief to which it may be entitled.

ANSWERING THE SECOND CAUSE OF ACTION
[STRICT PRODUCTS LIABILITY FAILURE TO WARN]

29. Lilly repeats and realleges with the same force and effect as if fully set forth herein its answers to each and every allegation contained in each paragraph incorporated by reference in Paragraph 29 of the Complaint.

30. Lilly denies the allegations contained in Paragraph 30 of the Complaint, except admits that Lilly researched, tested, developed, manufactured, marketed and sold Zyprexa® to independent pharmaceutical wholesalers. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 30 of the Complaint relating to the plaintiff and his physician.

31. Lilly denies the allegations contained in Paragraph 31 of the Complaint, except admits that information regarding the safety profile of Zyprexa® was contained in the FDA-approved labeling for Zyprexa®. Any characterization of the Zyprexa® product labeling that is inconsistent with the FDA-approved labeling for Zyprexa when the labeling is read in its entirety is denied.

32. Lilly denies the allegations contained in Paragraph 32 of the Complaint, except admits that information regarding the safety profile of Zyprexa® was contained in the FDA-approved labeling for Zyprexa®.

33. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 33 of the Complaint.

34. Lilly denies the allegations contained in Paragraph 34 of the Complaint, except admits that information regarding the safety profile of Zyprexa® was contained in the FDA-approved labeling for Zyprexa®.

35. Lilly denies the allegations contained in Paragraph 35 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations relating to the plaintiff.

36. Lilly denies the allegations contained in Paragraph 36 of the Complaint, except admits that information regarding the safety profile of Zyprexa® was contained in the FDA-approved labeling for Zyprexa®.

37. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 37 of the Complaint.

WHEREFORE, defendant Eli Lilly and Company requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that Lilly be awarded the

costs, disbursements, and attorney's fees incurred in the defense of this action, and that Lilly be granted any other relief to which it may be entitled.

ANSWERING THE THIRD CAUSE OF ACTION
[STRICT PRODUCTS LIABILITY/DEFECTIVE PRODUCT]

38. Lilly repeats and realleges with the same force and effect as if fully set forth herein its answers to each and every allegation contained in each paragraph incorporated by reference in Paragraph 38 of the Complaint.

39. Lilly denies the allegations contained in Paragraph 39 of the Complaint, except admits that Lilly researched, tested, developed, manufactured, marketed and sold Zyprexa® to independent pharmaceutical wholesalers. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 39 of the Complaint relating to plaintiff.

40. Lilly denies the allegations contained in Paragraph 40 of the Complaint.

41. Lilly denies the allegations contained in Paragraph 41 of the Complaint.

42. Lilly denies the allegations contained in Paragraph 42 of the Complaint, except admits that information regarding the safety profile of Zyprexa® was contained in the FDA-approved labeling for Zyprexa®. Any characterization of the Zyprexa® product labeling that is inconsistent with the FDA-approved labeling for Zyprexa® when the labeling is read in its entirety is denied.

43. Lilly denies the allegations contained in Paragraph 43 of the Complaint, except admits that information regarding the safety profile of Zyprexa® was contained in the FDA-approved labeling for Zyprexa®. Any characterization of the Zyprexa® product labeling that is inconsistent with the FDA-approved labeling for Zyprexa® when the labeling is read in its entirety is denied.

44. Lilly denies the allegations contained in Paragraph 44 of the Complaint.

45. Lilly denies the allegations contained in Paragraph 45 of the Complaint.

46. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 46 of the Complaint.

47. Lilly denies the allegations contained in Paragraph 47 of the Complaint.

48. WHEREFORE, defendant Eli Lilly and Company requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that Lilly be awarded the costs, disbursements, and attorney's fees incurred in the defense of this action, and that Lilly be granted any other relief to which it may be entitled.

ANSWERING THE FOURTH CAUSE OF ACTION
[NEGLIGENCE]

49. Lilly repeats and re-alleges with the same force and effect as if fully set forth herein its answer to each and every allegation contained in each Paragraph incorporated by reference in Paragraph 49 of the Complaint.

50. Lilly denies the factual allegations contained in Paragraph 50 of the Complaint; the remainder are legal conclusions to which no response is required.

51. Lilly denies the allegations contained in Paragraph 51 of the Complaint.

52. Lilly denies the allegations contained in Paragraph 52 of the Complaint.

53. Lilly denies the allegations contained in Paragraph 53 of the Complaint, except admits that information regarding the safety profile of Zyprexa® was contained in the FDA-approved labeling for Zyprexa®. Any characterization of the Zyprexa® product labeling that is inconsistent with the FDA-approved labeling for Zyprexa® when the labeling is read in its entirety is denied.

54. Lilly denies the allegations contained in Paragraph 54 of the Complaint.

55. Lilly denies the allegations contained in Paragraph 55 of the Complaint.

WHEREFORE, defendant Eli Lilly and Company requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that Lilly be awarded the costs, disbursements, and attorney's fees incurred in the defense of this action, and that Lilly be granted any other relief to which it may be entitled.

ANSWERING THE FIFTH CAUSE OF ACTION
[BREACH OF IMPLIED WARRANTY]

56. Lilly repeats and realleges with the same force and effect as if fully set forth herein its answer to each and every allegation contained in each paragraph incorporated by reference in Paragraph 56 of this Complaint.

57. Lilly denies the factual allegations contained in Paragraph 57 of the Complaint, except that Lilly admits that it researched, tested, developed, manufactured, marketed and sold Zyprexa® to independent pharmaceutical wholesalers.

58. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 58 of the Complaint.

59. To the extent that the allegations contained in Paragraph 59 of the Complaint contain legal conclusions no responsive pleading is required. Lilly denies the remaining allegations.

60. Lilly denies the allegations contained in Paragraph 60 of the Complaint.

61. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 61 of the Complaint.

WHEREFORE, defendant Eli Lilly and Company requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that Lilly be awarded the

costs, disbursements, and attorney's fees incurred in the defense of this action, and that Lilly be granted any other relief to which it may be entitled.

ANSWERING THE SIXTH CAUSE OF ACTION
[BREACH OF EXPRESS WARRANTY]

62. Lilly repeats and re-alleges with the same force and effect as if fully set forth herein its answer to each and every allegation contained in each paragraph incorporated by reference in Paragraph 62 of the Complaint.

63. Lilly denies the allegations contained in Paragraph 63 of the Complaint.

64. Lilly denies the allegations contained in Paragraph 64 of the Complaint.

65. Lilly denies the allegations contained in Paragraph 65 of the Complaint.

66. Lilly denies the allegations contained in Paragraph 66 of the Complaint.

67. Lilly denies the allegations contained in Paragraph 67 of the Complaint, except Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this Paragraph 67 relating to plaintiff and his physician.

68. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 68 of the Complaint.

69. Lilly denies the allegations contained in Paragraph 69 of the Complaint.

WHEREFORE, defendant Eli Lilly and Company requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that Lilly be awarded the costs, disbursements, and attorney's fees incurred in the defense of this action, and that Lilly be granted any other relief to which it may be entitled.

ANSWERING THE SEVENTH CAUSE OF ACTION
[FRAUD]

70. Lilly repeats and realleges with the same force and effect as if fully set forth herein its answer to each and every allegation contained in each paragraph incorporated by reference in Paragraph 70 of the Complaint.

71. Lilly denies the allegations contained in Paragraph 71 of the Complaint.

72. Lilly denies the allegations contained in Paragraph 72 of the Complaint.

73. Lilly denies the allegations contained in Paragraph 73 of the Complaint.

74. Lilly denies the allegations contained in Paragraph 74 of the Complaint, except Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this Paragraph 74 relating to plaintiff and his physician.

75. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 75.

76. Lilly denies the allegations contained in Paragraph 76 of the Complaint.

77. Lilly denies the allegations contained in Paragraph 77 of the Complaint.

78. Lilly denies the allegations contained in Paragraph 78 of the Complaint.

WHEREFORE, defendant Eli Lilly and Company requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that Lilly be awarded the costs, disbursements, and attorney's fees incurred in the defense of this action, and that Lilly be granted any other relief to which it may be entitled.

ANSWERING THE EIGHTH CAUSE OF ACTION
[FRAUD BY CONCEALMENT]

79. Lilly repeats and realleges with the same force and effect as if fully set forth herein its answer to each and every allegation contained in each paragraph incorporated by reference in Paragraph 79 of the Complaint.

80. To the extent that the allegations contained in Paragraph 80 of the Complaint contain legal conclusions no responsive pleading is required. Lilly denies the remaining allegations.

81. To the extent that the allegations contained in Paragraph 81 of the Complaint contain legal conclusions no responsive pleading is required. Lilly denies the remaining allegations.

82. Lilly denies the allegations contained in Paragraph 82 of the Complaint.

83. Lilly denies the allegations contained in Paragraph 83 of the Complaint, except that Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this paragraph relating to plaintiff and his physician.

84. Lilly denies the allegations contained in Paragraph 84 of the Complaint.

85. Lilly denies the allegations contained in Paragraph 85 of the Complaint.

86. Lilly denies the allegations contained in Paragraph 86 of the Complaint.

87. Lilly denies the allegations contained in Paragraph 87 of the Complaint, except Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this paragraph relating to plaintiff and his physician.

88. Lilly denies the allegations contained in Paragraph 88 of the Complaint.

89. Lilly denies the allegations contained in Paragraph 89 of the Complaint.

WHEREFORE, defendant Eli Lilly and Company requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that Lilly be awarded the costs, disbursements, and attorney's fees incurred in the defense of this action, and that Lilly be granted any other relief to which it may be entitled.

ANSWERING THE NINTH CAUSE OF ACTION
[UNJUST ENRICHMENT AS TO DEFENDANTS]

90. Lilly repeats and realleges with the same force and effect as if fully set forth herein its answer to each and every allegation contained in each Paragraph incorporated by reference in Paragraph 90 of the Complaint.

91. Lilly denies the allegations contained in Paragraph 91 of the Complaint.

92. Lilly denies the allegations contained in Paragraph 92 of the Complaint, except Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this paragraph relating to plaintiff.

93. Lilly denies the allegations contained in Paragraph 93 of the Complaint.

WHEREFORE, defendant Eli Lilly and Company requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that Lilly be awarded the costs, disbursements, and attorney's fees incurred in the defense of this action, and that Lilly be granted any other relief to which it may be entitled.

ANSWERING THE TENTH CAUSE OF ACTION
[WANTONNESS]

94. Lilly repeats and realleges with the same force and effect as if fully set forth herein its answer to each and every allegation contained in each paragraph incorporated by reference in Paragraph 94 of the Complaint.

95. Lilly denies the allegations contained in Paragraph 95 of the Complaint, except that Lilly admits that it researched, tested, developed, manufactured, marketed, sold and labeled Zyprexa® to independent pharmaceutical wholesalers.

96. To the extent the allegations contained in Paragraph 96 of the Complaint contain legal conclusions no responsive pleading is necessary.

97. Lilly denies the allegations contained in Paragraph 97(a)-(g) of the Complaint, except that Lilly admits that (1) it researched, tested, developed, manufactured, marketed, labeled and/or included warnings on Zyprexa®, and sold Zyprexa® to independent pharmaceutical wholesalers, and (2) information regarding the safety profile of Zyprexa® was contained in FDA-approved labeling for Zyprexa®. Any characterization of the Zyprexa® product labeling that is inconsistent with the FDA-approved labeling for Zyprexa® when the labeling is read in its entirety is denied.

98. Lilly denies the allegations contained in Paragraph 98 of the Complaint.

WHEREFORE, defendant Eli Lilly and Company requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that Lilly be awarded the costs, disbursements, and attorney's fees incurred in the defense of this action, and that Lilly be granted any other relief to which it may be entitled.

PRAYER FOR RELIEF

Lilly incorporates by reference, as though fully set forth herein, its answer to each and every allegation contained in each paragraph of the Complaint. Lilly denies all allegations concerning its conduct as set forth in paragraphs (a) and (b) of the Prayer for Relief and further denies that the plaintiff is entitled to any of the requested relief set forth in Paragraphs (a)-(m) of the Prayer for Relief.

FIRST AFFIRMATIVE DEFENSE

99. The Complaint fails to state a claim upon which relief can be granted against Lilly.

SECOND AFFIRMATIVE DEFENSE

100. Plaintiff's claims are barred, in whole or in part, by the statute of limitations.

THIRD AFFIRMATIVE DEFENSE

101. Venue is improper in this judicial district.

FOURTH AFFIRMATIVE DEFENSE

102. Some or all of plaintiff's claims are barred by the learned intermediary and/or sophisticated user doctrines. At all relevant times herein, plaintiff's prescribing physicians were in the position of sophisticated purchasers, fully knowledgeable and informed with respect to the risks and benefits of Zyprexa®.

FIFTH AFFIRMATIVE DEFENSE

103. The injuries, damages, and losses alleged in the Complaint, none being admitted, were caused in whole or in part by the negligence of the plaintiffs and/or others, over whom Lilly exercised no control, had no opportunity to anticipate or right to control, and with whom Lilly had no legal relationship by which liability could be attributed to it because of the actions of the plaintiff and/or others.

SIXTH AFFIRMATIVE DEFENSE

104. Plaintiff's alleged loss, damage, injury, harm, expense, diminution, or deprivation alleged, if any, was caused in whole or in part by plaintiff's failure to exercise reasonable care and diligence to mitigate his alleged damages.

SEVENTH AFFIRMATIVE DEFENSE

105. Plaintiff's claims are preempted by federal law in that Zyprexa® was manufactured and labeled in a manner consistent with the state of the art at the pertinent time and approved by the FDA.

EIGHTH AFFIRMATIVE DEFENSE

106. Some or all of plaintiff's claims are barred by the doctrines concerning unavoidably unsafe products, including, but not limited to, the operation of comments j and k to Section 402A of the Restatement (Second) of Torts and/or barred by defenses available under the Restatement (Third) of Torts.

NINTH AFFIRMATIVE DEFENSE

107. Plaintiff's breach of warranty claims are barred because plaintiff failed to give timely notice of any alleged breach of warranty to Lilly; plaintiff did not reasonably rely upon any alleged warranty; plaintiff failed to satisfy all conditions precedent or subsequent to the enforcement of such warranty; and the warranty was appropriately disclaimed, excluded or modified.

TENTH AFFIRMATIVE DEFENSE

108. Plaintiff's claims are barred in whole or in part by the applicable provisions of the United States Constitution, the Alabama Constitution, and/or the applicable

Constitution of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. These provisions include, but are not limited to, the First Amendment to the Constitution of the United States and/or Article I, Section 4 of the Constitution of the State of Alabama because Lilly's commercial speech regarding Zyprexa® was neither false nor misleading.

ELEVENTH AFFIRMATIVE DEFENSE

109. Lilly alleges that plaintiff was fully informed of the risks of the use of the product made the subject of this action by the treating physician, and the plaintiff's informed consent and assumption of the risks are pleaded as an affirmative defense.

TWELFTH AFFIRMATIVE DEFENSE

110. Plaintiff's claim for punitive damages violates, and it is therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America on grounds including the following:

(a) It is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose punitive damages, which are penal in nature, against a civil defendant upon the plaintiffs satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;

(b) Procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution;

(c) The procedures pursuant to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against defendant, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;

(d) The procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;

(e) The procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(f) The procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(g) The procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution;

(h) The award of punitive damages to plaintiff in this action would constitute a deprivation of property without due process of law; and

(i) The procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

THIRTEENTH AFFIRMATIVE DEFENSE

111. With respect to plaintiff's demand for punitive or exemplary damages, Lilly specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damages awards, including but not limited to, those standards of limitation which arose in BMW of North America v. Gore, 517 U.S. 559 (1996), Cooper Industries, Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424 (2001), and State Farm Mutual Automobile Ins. Co. v. Campbell, 530 U.S. 408 (2003).

FOURTEENTH AFFIRMATIVE DEFENSE

112. Punitive damage awards in Alabama are unconstitutional because they are penal in nature yet defendants in civil actions are not awarded the same procedural safeguards accorded to criminal and other defendants under the Fourth, Fifth, Sixth, Eighth, and Fourteenth Amendments to the United States Constitution; therefore, plaintiff cannot recover punitive damages.

FIFTEENTH AFFIRMATIVE DEFENSE

113. Punitive damage awards in Alabama are not governed by any specific or adequate standards, are not based upon rational distinctions, do not serve any legitimate state interest, are necessarily vague and arbitrary, and therefore are in violation of the due process and equal protection provisions of both the Fifth, Eighth, and Fourteenth Amendments to the United States Constitution, and Article I, Sections 1, 6, and 22 of the Constitution of Alabama; therefore, plaintiff cannot recover punitive damages.

SIXTEENTH AFFIRMATIVE DEFENSE

114. The plaintiff's claims for punitive damages are barred by § 6-11-27 and 6-11-20 of the Alabama Code.

SEVENTEENTH AFFIRMATIVE DEFENSE

115. The plaintiff's claims for punitive damages are subject to the limitations contained in § 6-11-21 of the Alabama Code.

EIGHTEENTH AFFIRMATIVE DEFENSE

116. Plaintiff's claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction, in that the Food and Drug Administration of the United States Department of Health and Human Services ("FDA") is charged under the law with regulating prescription drugs, including Zyprexa®, and is specifically charged with determining the content of the warnings and labeling for prescription drugs. The granting of the relief prayed for in the plaintiff's Complaint would impede, impair, frustrate or burden the effectiveness of such federal law and would violate the Supremacy Clause (Art. VI, cl. 2) of the United States Constitution.

NINETEENTH AFFIRMATIVE DEFENSE

117. To the extent plaintiff's claims are based on alleged misrepresentations made to the FDA, such claims are barred pursuant to Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001).

TWENTIETH AFFIRMATIVE DEFENSE

118. Any verdict or judgment rendered against Lilly must be reduced by those amounts that have been, or will, with reasonable certainty, replace or indemnify plaintiff, in

whole or in part, for any past or future claimed economic loss, from any collateral source such as insurance, social security, worker's compensation or employee benefit programs.

TWENTY-FIRST AFFIRMATIVE DEFENSE

119. Plaintiff's purported allegations of misrepresentation and fraud do not comply with Rule 9(b) of either the Federal Rules of Civil Procedure or the Alabama Rules of Civil Procedure, in that they fail to state a cause of action as a matter of law because, among other deficiencies, plaintiff fails to plead with specificity any false misrepresentation as to a material fact and/or reliance on the part of plaintiff upon any such material fact.

TWENTY-SECOND AFFIRMATIVE DEFENSE

120. Lilly hereby gives notice that it intends to rely upon such other defenses as may become available or apparent during the course of discovery and thus reserves the right to amend this list to assert such defenses.

DEMAND FOR TRIAL BY JURY

121. Defendant demands trial by Jury for all issues in this action.

WHEREFORE, defendant Eli Lilly and Company requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that Lilly be awarded the costs, disbursements, and attorney's fees incurred in the defense of this action, and that Lilly be granted any other relief to which it may be entitled.

s/ James C. Barton, Jr.

James C. Barton, Jr. (BAR014)

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the above and foregoing with the Clerk of the Court on October 6, 2005, using the CM/ECF system, which will send notification of such filing to the following:

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s/ Alan D. Mathis
Of Counsel

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